REMARKS

Claims 1-6 are pending in the present Application.

Claims 1 and 2 have been amended. No new matter has been added as support for these amendments can be found at least at p. 3, lines 1-3 and p. 1, lines 28-30.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-6 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office action alleged that the claims contain subject matter which was not described in the Specification in such a way as to enable one skilled in the art to make or use the invention. Applicants respectfully traverse this rejection.

In making the rejection, the Examiner stated that the art of this invention is viewed as a highly unpredictable one, and that the Specification provides only a single observation of the claimed SNPs from one patient from a small, ethnically homogeneous diseased population, with no control of a normal, healthy population. Further, the Examiner stated that the Specification is non-enabling because it does not even provide guidance to overcome problems that were art-recognized, at the time of filing, with respect to associating polymorphisms with susceptibility to specific conditions (See Wacholder, Ioannidis, and Lucentini). (Office Action dated 11/27/2006, pages 9-10)

Applicants note that Claim 1 is limited to an ethnic Korean group and is thus supported by the detailed description. The specification notes at p. 8, lines 4-5, that distributions of MODY genes are different depending on racial and geographic characteristics.

Applicants note that sequencing of 97 patients corresponds to sequencing of 194 human chromosomes, which increases the power of accurate observation of a polymorphism in the sequencing experiment. Further, Applicants note that the sequences obtained by direct sequencing of the Korean patients were compared to DNA sequences present in the NCBI database (p. 7, lines 12-13) and that the specification asserts that the claimed nucleic acid fragment can be used as a probe or primer in diagnosis of MODY (p. 8, lines 7-8).

Applicants note that Wacholder et al. was published after the priority date of the pending application. However, Wacholder et al. is largely concerned with the statistical problems arising when testing several haplotypes and SNPS in thousands of genes (p. 434, col. 2, "Historical Overview"). Such large numbers of possible combinations to be tested statistically result in a large number of false positives; standard tests to evaluate the statistical relevanceof a given association (e.g., p-value) are inadequate and need to be "adjusted" to account for the number of tests conducted. In the pending application, only 1 novel polymorphism in SEQ ID NO:1 was discovered and only that polymorphism is considered in claim 1. Therefore, the statistical problems associated with false positives resulting from testing of many hypotheses is not relevant in the context of the current application.

Applicants request reconsideration and withdrawal of the §112, 1st paragraph, rejection of clams 1-6.

Claim Rejections Under 35 U.S.C. § 102(b) and (e)

Claims 1-4 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by Emens et al (PNAS (1992) 89(16): 7300-7304)(hereiafter "Emens"). (Office Action dated 11/27/2006, page 10) Applicants respectfully traverse this rejection.

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987).

In making the rejection, the Examiner stated that Emens teaches a nucleic acid fragment comprising a polymorphic site of SEQ ID No: 1 having adenine at position 1699 and comprising more than 10 contiguous nucleotides of SEQ ID No: 1. (Office Action dated 11/27/2006, page 10) The Examiner provided a nucleotide sequence alignment generated from GenBank Accession No. M95297, deposited by Emens and cited in the Emens reference. (Office Action dated 11/27/2006, pages 11-14) Furthermore, with regard to Claim 2, the Examiner stated that the fragment disclosed by Emens comprises 22 contiguous nucleotides. (Office Action dated 11/27/2006, page 14) With regard to Claims 3 and 4, the Examiner stated that Emens teaches and allele-specific oligonucleotide hybridizing to the fragment disclosed by Emens. (Office Action dated 11/27/2006, page 14)

Emens is generally directed to the expresin of HNFα in the pancreatic islet β-cell-derived

Hamster insulinoma cell line (HIT). Furthermore, Emens discloses a nucleic acid encoding HNF1a expressed in a HIT cell line (*Mesocricetus auratus* (golden hamster)), M95297. The sequence M95297 does not disclose the presence of the polymorphism corresponding to the polymorphic site of SEQ ID NO: 1 having adenine (A) at position 1699. Emens does not disclose a nucleic acid fragment comprising a polymorphic site of SEQ ID NO: 1 having adenine (A) at position 1699 derived from a human patient or a human cell line.

As amended, independent Claim 1 is directed to a nucleic acid fragment comprising a polymorphic site of SEQ ID NO: 1 having adenine (A) at position 1699 and comprising more than 23 contiguous nucleotides derived from nucleotide sequence set forth in SEQ ID NO: 1, or a complement thereof, wherein the nucleic acid fragment is for the diagnosis of maturity onset diabetes of the young (MODY) or the risk of MODY in ethnic Korean humans. As indicated above, Emens discloses a nucleotide sequence derived from *Mesocricetus auratus* (golden hamster) which can be aligned with SEQ ID NO:1, and in such alignment Emens sequence M95297 aligns with 22 contiguous nucleotides of SEQ ID No: 1 which comprise the a polymorphic site of SEQ ID No: 1 having adenine at position 1699. However, Emens does not disclose a nucleotide sequence comprising a polymorphic site of SEQ ID NO: 1 having adenine (A) at position 1699 and comprising more than 23 contiguous nucleotides derived from nucleotide sequence set forth in SEQ ID NO: 1. Therefore, Emens does not teach all elements and therefore cannot anticipate the claimed invention.

In addition, Emens does not disclose a nucleic acid fragment comprising a polymorphic site of SEQ ID NO: 1 having adenine (A) at position 1699 derived from a human patient or a human cell line.

Further, Emens do not disclose that the nucleic acid is associated with MODY in ethnic Korean humans. Therefore, Emens can not teach a nucleic acid fragment wherein the nucleic acid fragment is for the diagnosis of maturity onset diabetes of the young (MODY) or the risk of MODY in ethnic Korean humans, and therefore does not teach all the elements of the claimed invention. For these reasons at least, Emens does not anticipate the claimed invention. Applicants respectfully request a withdrawal of the §102(b) rejection over Emens and an allowance of the claims.

Claims 1-6 stand rejected under 35 U.S.C. § 102(e), as allegedly anticipated by Wang (US 2004/0181048 A1; filed August 8, 2001). (Office Action dated 11/27/2006, page 14) Applicants respectfully traverse this rejection.

To anticipate a claim, a reference must disclose each and every element of the claim. *Lewmar Marine v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987).

In making the rejection, the Examiner stated that Wang teaches a nucleic acid fragment comprising more than 10 contiguous nucleotides of SEQ ID NO.: 3 and the polymorphic nucleotide T at position 29. (Office Action dated 11/27/2006, page 14)

For the record, Applicants note that the cited sequence of Wang (SEQ ID NO: 519026) is stated in the Office Action to be 678 nucleotides in length and was not available for downloading by the Applicant from either PSIPS (which showed no sequences available for this published application) or from PAIR (which did show a sequence listing present which was larger than the allowed download size). The Examiner indicated in response to my request regarding the sequence on February 23, 2007, that the sequence itself was not annotated by Wang to indicate the presence of a polymorphism at a position in the alignment corresponding to nucleotide 29 of SEQ ID NO:3 of the present application. Figure 2 of Wang, putatively showing all of Wang's polymorphisms with context sequence, was not available. Therefore although Wang provides a much longer sequence and discloses SNP probes in para. [0010], no published information of Wang discloses the presence of a SNP at a position in the alignment corresponding to nucleotide 29 of SEQ ID NO:3 of the present application and therefore Wang et al. do not disclose a nucleic acid fragment comprising a polymorphic site of SEQ ID NO:3 having T at position 29 and comprising at least 10 contiguous nucleotides of SEQ ID NO:3.

However, to move prosecution forward, Applicants have amended claim 1. As amended, reference to SEQ ID No: 3 in Claim 1 has been deleted. Wang does not disclose a nucleic acid fragment comprising more than 23 contiguous nucleotides of SEQ ID No: 1 having adenine (A) at position 1699, and therefore does not teach all elements of the claimed invention. For this reason at least, Wang does not anticipate the present invention. Applicants respectfully request a withdrawal of the §102(e) rejection over Wang and an allowance of the claims.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance are requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

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